UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

MONROE DIVISION

BRYANT LYLES	**CIVIL ACTION NO. 15-0910**
VERSUS	**JUDGE ROBERT G. JAMES**
MEDTRONIC, INC., ET AL.	**MAG. JUDGE JOSEPH PEREZ-MONTES**

RULING

Plaintiff Bryant Lyles ("Lyles") brought this lawsuit as a result of injuries he suffered after a May 10, 2013 surgery in which his surgeon allegedly implanted two devices: the Atlantis Translational Anterior Cervical Plate System ("Atlantis Plate") and the Infuse Bone Graft Device ("Infuse").[1] In his Third Amended Complaint, Lyles asserts claims against Defendant Medtronic Sofamor Danek USA, Inc. (a subsidiary of Medtronic, Inc.) ("MSD") under the Louisiana Products Liability Act ("LPLA") that the Alantis Plate was defectively constructed, composed, and designed. He also asserts state law claims against MSD and Defendant Medtronic, Inc. ("Medtronic") under the Louisiana Unfair Trade Practices and Consumer Protection Act ("LUPTA") and for fraud based on their alleged creation and use of false and misleading information concerning Infuse's safety and effectiveness.

Pending before the Court are MSD's Motion to Dismiss Plaintiff's Third Amended Complaint and Request for Judicial Notice [Doc. No. 31] and Medtronic's Motion to Dismiss

[1]Defendants deny that Infuse was implanted during Lyles' surgery and have filed a Motion for Partial Summary Judgment [Doc. No. 45] on this claim, but the Court assumes for purposes of this Ruling that Lyles' allegations are true.

Plaintiff's Third Amended Complaint [Doc. No. 32].[2] MSD moved the Court, pursuant to Federal Rule of Evidence 201, to take judicial notice of certain Food and Drug Administration ("FDA") documents attached as Exhibits 1-6 to its motion and to dismiss all claims against it. Medtronic moved the Court to dismiss all claims against it based on the arguments contained in MSD's Motion to Dismiss, which it adopted, and on the additional basis that Lyles' claims against it are prescribed.

On November 23, 2015, Magistrate Judge James D. Kirk issued a Report and Recommendation [Doc. No. 56]. Magistrate Judge Kirk recommended that the Court find as follows:

(1) Lyles' claims against Medtronic are prescribed, its Motion to Dismiss should be granted, and the claims against it should be dismissed with prejudice.

(2) Lyles has set forth factual allegations sufficient to support his LPLA claim that the Atlantis Plate was defective in its construction or composition.

(3) Lyles has not set forth factual allegations sufficient to support his LPLA claim that the Atlantis Plate was defective in design because he failed to assert that an alternative design for the product, capable of preventing his damage, existed at the time the Atlantis Plate left MSD's control. However, Magistrate Judge Kirk recommended that the Court give Lyles leave to amend his Complaint a fourth time to properly assert this claim.

(4) Lyles' claims of fraud and under LUPTA are barred by the exclusivity provision of the LPLA, the Motions to Dismiss should be granted, and these claims against both Defendants should be dismissed with prejudice. Magistrate Judge Kirk did not

[2]The Court will refer to these motions collectively as Motions to Dismiss.

> recommend that the Court grant Lyles leave to amend his Complaint to properly assert this claim because any LPLA failure to warn claim would be expressly and/or impliedly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360, *et seq.*, which amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*.

On December 8, 2015, Lyles filed objections [Doc. No. 61] to the Report and Recommendation. Defendants timely filed responses to those objections. [Doc. No. 69]. With leave of Court, Lyles filed a reply memorandum. [Doc. No. 73].

Having reviewed the entire record in this matter, the Court finds that Magistrate Judge Kirk correctly stated and applied the law. The Court hereby ADOPTS his Report and Recommendation. The Court issues this Ruling for the limited purposes of clarifying and supplementing the Report and Recommendation and addressing arguments raised for the first time in the objections.

First, to the extent that MSD moved the Court to take judicial notice of the FDA documents attached as Exhibits 1-6 to its Motion to Dismiss [Doc. No. 31], the motion is GRANTED. Given his analysis and conclusion, it was not necessary for Magistrate Judge Kirk to consider these documents. Nevertheless, the Court finds it appropriate for these exhibits to be made part of the record. *See Sons v. Medtronic, Inc.*, 915 F. Supp. 2d 776, 781 (W.D. La. 2013) (a court "may take judicial notice of and consider the public records of the FDA . . . without transforming [a] motion [to dismiss] into a motion for summary judgment.") (citations omitted).[3]

[3]The Court has adopted the Report and Recommendation of Magistrate Judge Kirk, but in conducting a *de novo* review of the entire record in this matter, the Court reviewed the FDA records while considering the parties' arguments on preemption. Ultimately, the Court did not find it necessary to rely on those documents in reaching its conclusions.

Second, the Court has considered Lyles' additional arguments that his fraud and LUPTA claims against Medtronic are not prescribed. Magistrate Judge Kirk found, and the Court agrees, that Lyles' claims against Medtronic prescribed well before it was renamed as a defendant in the Third Amended Complaint.

In his objections, Lyles argues that his claims against Medtronic in the Third Amended Complaint are timely because MSD and Medtronic are joint tortfeasors; because Medtronic and Lyles' surgeon, Dr. Sin, are joint tortfeasors; or because counsel did not receive his medical records until February 6, 2015. The Court disagrees.

"When the plaintiff's basis for claiming interruption of prescription is that the newly added defendant is a joint tortfeasor with a defendant who was timely sued, then the plaintiff bears the burden of proving that joint tortfeasor status." *McKenzie v. Imperial Fire and Cas. Ins. Co.*, 2012-1648 (La. App. 1st Cir. 7/30/13); 122 So.3d 42, 47 (citing *Wheat v. Nievar*, 2007-0680 (La. App. 1st Cir. 2/8/08); 984 So.2d 773, 775). Additionally, the plaintiff also bears "the burden of establishing that prescription had been timely interrupted against a joint tortfeasor." *Id.* at 776. With regard to MSD, Lyles has failed to meet his burden. In his original Petition, Amended Complaint, and Second Amended Complaint, Lyles asserted only LPLA claims and only against one defendant. In the first two pleadings, he listed Medtronic as the lone defendant on the Atlantis Plate LPLA claim. In the third pleading (the Second Amended Complaint), MSD was substituted for Medtronic, and the Infuse LPLA claim was added, so that his two LPLA claims were again made against only one defendant–this time, MSD. Lyles never alleged that Medtronic and MSD were joint tortfeasors. It is only in his Third Amended Complaint, the fourth pleading he filed, that Lyles has attempted to reassert claims against Medtronic and, for the first time, to make it a joint tortfeasor with MSD.

Under these unique facts, Lyles has failed to establish that his substituted claims against MSD interrupted prescription. His claims against Medtronic had already prescribed before the Third Amended Complaint was filed.

With regard to Dr. Sin, Lyles also fails to meet his burden. Neither Lyles' Third Amended Complaint nor any prior pleadings raise allegations about Dr. Sin's tortious conduct. Lyles has never pointed to his claims against Dr. Sin until this eleventh hour attempt to re-name Medtronic as a defendant and assert new claims against it. Even if Lyles' January 12, 2015 lawsuit against Dr. Sin served to interrupt prescription against Medtronic initially, the Court would have to disregard Lyles' own decision to voluntarily substitute MSD for Medtronic as the sole Defendant, effectively dismissing his claims against Medtronic in June 2015.

With regard to his Infuse claim, Lyles has failed to show that prescription began to run at a later date. As Defendants point out, prescription began to run on Lyles' claims on February 13, 2014, when he learned of his injury. Lyles' argument that he has a separate accrual date for the Infuse claim (i.e. for each possible theory of or basis for recovery) is without merit.[4] Thus, for these reasons and those set forth in Magistrate Judge Kirk's Report and Recommendation, Lyles' claims against Medtronic are prescribed, and its Motion to Dismiss is GRANTED.

Finally, the Court finds that Magistrate Judge Kirk correctly analyzed Lyles' fraud and LUPTA claims. Although the parties have made extensive arguments regarding preemption,

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[4]To the extent that Lyles is attempting to make an argument under the doctrine of *contra non valentum*, he has failed to show that he did not know and it was not **reasonably knowable** that he had a claim based on the use of Infuse prior to counsel's receipt of his medical records on February 6, 2015. *See Wimberly v. Gatch*, 93-2361 (La. 4/11/94); 635 So.2d 206, 211 (under the fourth category recognized in the jurisprudential doctrine of *contra non valentum*, prescription is suspended "[w]here some cause of action is not known or reasonably knowable by the plaintiff, even though his ignorance is not induced by the defendant.").

Magistrate Judge Kirk found, and the Court agrees, that the fraud and LUPTA claims are barred by the exclusivity provision of the LPLA. Even in the Third Amended Complaint, Defendants[5] are alleged to have "designed, manufacture[d], and market[ed] the Infuse."[6] [Doc. No. 29, ¶5]. Accepting Lyles' allegations as true, MSD and Medtronic engaged in a fraudulent marketing campaign using false research to support claims about the efficacy and safety of Infuse.[7] Such claims are tantamount to an LPLA failure to warn claim. However, Magistrate Judge Kirk also concluded that permitting Lyles to amend to add an LPLA failure-to-warn claim would be futile because that claim would be preempted under the Medical Device Amendments to the FDCA, 21 U.S.C. § 301, *et seq.*[8]

Accordingly, for the foregoing reasons and for those reasons set forth in the Report and Recommendation of Magistrate Judge Kirk, Medtronic's Motion to Dismiss [Doc. No. 32] is GRANTED, and the claims against it are DISMISSED WITH PREJUDICE as prescribed and, alternatively, as barred by the exclusivity provision of the LPLA. MSD's Motion to Dismiss [Doc.

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[5]The Court has determined that any claims against Medtronic have prescribed, but addresses the substantive arguments on Lyles' fraud and LUPTA claims in the alternative.

[6]It is undisputed that MSD manufactured Infuse, not Medtronic, but the allegations are as stated, and the claims are made against Medtronic, according to Lyles' own words, as either a designer, manufacturer, or marketer.

[7]Lyles argues that Defendants did not produce marketing materials, but false medical research; however, the point of such studies and research could only be to market Infuse to their targeted audience.

[8]Although the Court need not reach this issue, even if the fraud and LUPTA claims are not barred by the exclusivity provision of the LPLA, they do appear to be preempted. *See Bass v. Stryker*, 669 F.3d 501 (5th Cir. 2012) (plaintiff's misrepresentation claim under the Texas Deceptive Trade Practices Act was "essentially" a failure to warn claim which was preempted by the Medical Device Amendments to the FDCA).

No. 31] is GRANTED IN PART and DENIED IN PART. To the extent that MSD moves the Court to take judicial notice of FDA documents attached as Exhibits 1-6, the motion is GRANTED. Further, to the extent that MSD moves for dismissal of the fraud and LUPTA claims against it, the motion is also GRANTED. To the extent that MSD moves for dismissal of Lyles' claim under the LPLA that the Atlantis Plate was defectively constructed or composed, the motion is DENIED. To the extent that MSD moves for dismissal of Lyles' claim under the LPLA that the Atlantis Plate was defectively designed, the motion is DENIED AT THIS TIME. Lyles shall have fourteen (14) days from the date of this Ruling to amend his Third Amended Complaint to properly allege a design defect claim. If he fails to do so, for the reasons stated in the Report and Recommendation of Magistrate Judge Kirk, the Court will dismiss his defective design claim with prejudice.

MONROE, LOUISIANA, this 20th day of January, 2016.

ROBERT G. JAMES
UNITED STATES DISTRICT JUDGE